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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,784	11/03/2003	Jacques M. Dulin	7175-004US	5515

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/700,784	**Applicant(s)** DULIN, JACQUES M.	
	Examiner Leslie A. Royds	**Art Unit** 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 September 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☒ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-4 and 6-15*.
   Claim(s) withdrawn from consideration: *5 and 16-20*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

Leslie A. Royds
Patent Examiner
Art Unit 1614

25 SEP 06

Continuation of 3. NOTE:

Applicant's amendments, filed September 18, 2006, will not be entered because the proposed amendments are replete with numerous limitations that have neither been previously searched nor considered during the course of prosecution of the originally filed claims and those amended following the first non-final Office Action and the supplemental amendment to the claims following the telephonic interview with Applicant. Accordingly, the amendments do not place the claims into better form for appeal by materially reducing or simplifying the issues for appeal because the amendments are directed to new limitations that raise new issues under, for example, 35 U.S.C. 112, first paragraph, and, therefore, do not simplify the pending issues, but actually add new issues for consideration. For example, Applicant's limitation directed to wherein "said cotton roll substrate retains its integrity upon being massaged by a buccinator muscle adjacent said buccal vestibule for an extended period of treatment time of up to an hour" has not been previously considered and would raise a new issue that would require further search and consideration.

Additionally, it is noted that the proposed claim amendments raise the issue of new matter that fails to find adequate written support as required by 35 U.S.C. 112, first paragraph. For example, Applicant now proposes to claim the use and impregnation of a topical oral medication into the disposable cotton roll "at dosage amounts substantially lower than conventional mouthwash", where the only written support Applicant provides in support of this limitation is a specific numerical range of mouthwash to be used in the disposible cotton roll. While such a dosage amount may indeed be less than what is used conventionally, the disclosure of an exemplary range of dosage amounts does not provide adequate written support as required by 35 U.S.C. 112, first paragraph, for "any" dosage amount that is substantially lower than the conventional amount of mouthwash.

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant's after-final amendments proposes amendments to presently pending claims 1-2, 5 and 10-13, cancellation of claims 16-20 and presents additional remarks in response to the rejections raised by the Examiner in the final rejection of 20 June 2006. The remarks have been carefully considered in their entirety, but are not persuasive for the following reasons:

Applicant states that the restriction requirement made a scientifically unsupported statement as the basis of restricting claim 5 between benzoic acid and boric acid and relies upon the Office Action where it asserts that, "The claimed product can be employed in a materially different process, such as insertion of the cotton roll impregnated with the antimicrobial agent, benzoic acid, directly into a wound as a plug to promote antimicrobial action and healing."

Applicant appears to be confusing the requirement for restriction between patentably distinct inventions, i.e., in the present case, the claimed delivery system and the claimed method for oral hygiene, with the requirement for election of species. The assertion that the claimed product can be employed in a materially different process as stated supra was the basis for requiring restriction between the claimed delivery system and the claimed method. It was not relied upon to "restrict" benzoic acid from boric acid. This was done as an election of species of a single topical oral medication. Therefore, Applicant's remarks regarding Dr. Stillman's discussion of wound infection have been duly noted, but are not persuasive in establishing error in the propriety of the restriction requirement.

Applicant further asserts that the Examiner is incorrect in stating that the claimed delivery system could be used in an allegedly materially different process, such as the use of a cotton roll impregnated with benzoic acid as a wound plug. First, it is noted that, in accordance with the MPEP at 806.05(h)[R-3], "The burden is on the Examiner to provide an example, but the example need not be documented." Therefore, Applicant's assertions that this is an unsubstantiated example are not persuasive because the Examiner is not required by the MPEP to document the example provided. Additionally, Applicant's allegation that such a proposed use could not be accomplished rests upon the argument that were one to insert a cotton roll impregnated with benzoic acid mouthwash into a wound, that one would cause contact dermatitis. This is an inherently flawed argument because: 1) the example proposed the use of benzoic acid itself, which is a known antibacterial agent, not benzoic acid mouthwash, and 2) insertion of a wound plug is common practice in the art to assist granulation of tissue in deep wound healing so as not to allow the skin to heal over before the subcutaneous tissue had healed, thereby causing an abscess.

Applicant's remarks regarding the "mischaracterization of the invention" based upon its intended use have been noted, but are also not persuasive. Applicant is reminded that the presently claimed delivery system is, according to the statutory categories of invention that can be claimed in US patent practice, a "composition" of matter insofar as it is composed of a cotton roll and a topical oral medication. Applicant is not prohibited from claiming such an invention, however, it is noted that whatever process that Applicant intends to use the composition of matter for is irrelevant to the composition itself because it does not structurally or materially change the physical components of the composition itself. The Office is not arbitrarily choosing to ignore Applicant's limitations. Each and every limitation has been fully considered to determine whether such limitations provide a physical or structural limitation to the overall generic structure of the claimed delivery platform. Where no such physical or structural limitation is made, the limitation is not patentably limiting to the composition. See, for example, MPEP 2111.02[R-3].

The restriction requirement is reconsidered, but again is found to remain proper and is grounded firmly and appropriately in the teachings of the MPEP at 800. Applicant's attention is directed thereto.

Applicant argues that the rejection set forth under 35 U.S.C. 103(a) is a "bag of parts" rejection, relies upon Applicant's specification, and is unsupported by any factual basis, motivation or evidence. This argument is not persuasive because Applicant has not overcome the rejection as it was set forth in the previous Office Action and the motivation that was provided for each and every modification that was asserted would have been obvious to one of ordinary skill in the art. Applicant's attention is directed to the rejection as it was set forth in the previous Office Action, which will not be repeated in total or in part herein so as not to burden the record.

Applicant states that the PTO has ignored all of the physical elements of the claimed invention. This is not persuasive. Applicant is directed to each and every cited reference, which provides not only a teaching, but also a motivation to use or modify, the reference to Masci to provide all of the physically required elements of the claimed invention.

Applicant further states that the motivation to combine references must come from the references, "not out of mid air or the desire for better results" (see paragraph bridging pages 17-18). However, Applicant is reminded that an express motivation to combine is not required to be explicitly stated in the prior art in order to construct a finding of obviousness. Please reference MPEP §2145(X), which states, "However, there is no requirement that an express, written motivation to combine must appear in the prior art references before a finding of obviousness." The motivation to combine the references is legitimate and is clearly supported by the fact that improved results would have motivated the skilled artisan to combine the references to enhance the therapeutic benefit or effect. This is not motivation "out of midair", but rather a realistic motivation to improve upon what was already known, and generally available to, the skilled artisan at the time of the invention.

Applicant states the prima facie case of obviousness must rest on proven facts, not opinion or conjecture of the Examiner and that it is "procedurally impossible for an Applicant to rebut a non-properly proven prima facie case where there is no evidence." (see page 18 of Applicant's remarks). This is not the present case. The prima facie case of obviousness has been supported not only by references, but also scientific reasoning and motivation. Nowhere in the Office Action does the rejection take the position that it is the opinion or conjecture of the Examiner. Accordingly, the burden is shifted to Applicant to demonstrate patentable distinction of the claimed invention over the prior art in preponderance of the evidence that has already been presented. Please see the rejection set forth under 35 U.S.C. 103(a) in the previous Office Action.

The amendments are not persuasive, raise new issues of search, consideration and new matter and will not be entered. Accordingly, the claims remain rejected for the reasons of record set forth in the previous Office Action. Applicant's attention is directed thereto.

Continuation of 13. Other:

Regarding Applicant's submission of the Information Disclosure Statement (IDS) of September 18, 2006, it is noted that the IDS was accompanied by the appropriate certification under 37 C.F.R. 1.97(e)(2), but failed to be accompanied by the appropriate payment of fees under 37 C.F.R. 1.17(p).

Accordingly, failure to file the appropriate payment under 37 C.F.R. 1.17(p) results in non-entry and non-consideration of the IDS submission.

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Ardin H. Marschel 9/28/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER